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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,108

02/04/2004

Jantzen A. Cole

702.117

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04/01/2008

WRIGHT MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002-9501

EXAMINER

WALKER, AMANDA H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,108	Applicant(s) COLE ET AL.	
	Examiner AMANDA H. WALKER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-16 is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-6 and 8 are cancelled. Claims 7 and 9-16 are amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ison et al. (United States Patent Number 5,697,981) in view of Randolph et al., as evidenced by Koslowski (United States Patent Number 5,015,449) and Randel et al. (United States Patent Number 1,901,051)

Regarding Claim 7: Ison et al. teaches a method of treating bone defects comprising a step of mixing a calcium sulfate powder (4:10-40, specifically 4:38) with water (6:20-25) to produce an injectable (9:60) bone graft material in the form of a paste. The calcium sulfate powder may make up to 30% of the total dry cement composition (4:33). The claim as broadly worded does not exclude the possibility of other steps such as mixing other dry components in with the diluent as Ison et al. teaches. Ison et al. further teaches a step of injecting the material into a bone defect (9:55-65). Ison et al. does not elaborate on the details of the calcium sulfate dry component.

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Randolph et al. teaches a bone implant (15:5-10) that begins as a paste (3:55-65) and hardens into a pellet. The paste is made of water and alpha-calcium sulfate hemihydrate powder (3:55-65). The calcium sulfate powder consists essentially of alpha-calcium sulfate hemihydrate with a purity between 98-100% (2:15-25). The limitation "low water carrying capacity" is not adequately defined in the specification or the claims to exclude the composition taught by Randolph et al., because any dried cement-like substance can be considered to have "low water carrying capacity". Furthermore, "stubby rod-like crystals" are assumed to be an implicit quality of alpha calcium sulfate hemihydrate in absence of any evidence that would point otherwise and in view of suggestions taught by Randel et al. (page 6, line 55) and Koslowski (8:35-45). Ison et al. and Randolph et al. are combinable because they are from the same field of endeavor, namely, bone graft cements using calcium sulfate. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the vaguely described calcium sulfate powder used by Ison et al. with the details of a calcium sulfate powder taught by Randolph et al., and one would have been motivated to do so in order to acquire greater predictability in dissolution rates (Randolph et al., FIGS. and 1:64+).

Response to Arguments

Applicant's arguments filed 1-07-08, with respect to the rejection(s) of claim(s) 7 under Randolph et al. in view of Constantz et al. in view of Tiemann et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference, Ison et al.

Applicant's arguments filed 1-07-08, with respect to claims 9-16 have been fully considered and are persuasive. The rejections of claims 9-16 have been withdrawn.

Allowable Subject Matter

Claims 9-16 are allowed.

The following is an examiner's statement of reasons for allowance: To the Examiner's knowledge, no reference contains the specific compressive strengths of the claimed graft paired with the specific times at which said strengths occur.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

AHW
3-27-08